Application No.: 10/776,333

AMENDMENTS TO THE CLAIMS

Please amend the claims so that they read as follows:

- (Currently Amended) A transmucosally delivered controlled release composition which upon administration exhibits substantially linear absorption rates, the composition comprising:
- (a) an therapeutically analgesically effective amount of morphine base monohydrate;
- (b) an effective amount of a controlled release chitosan polymer in an amount effective to provide substantially linear absorption rates upon administration; and optionally comprising:
 - (c) one or more antimicrobial agents;
 - (d) one or more antioxidants; and
 - (e) water;

wherein the molecule to molecule ratio of morphine base monohydrate to the controlled release chitosan polymer ranges from about 1:1 to about 100,000:1 to provide the substantially linear absorption rates upon administration.

- (Previously Presented) The composition of claim 1, wherein the molecule to
 molecule ratio of the morphine base monohydrate to the controlled release chitosan polymer
 ranges from about 5,000:1 to about 80,000:1.
 - 3. (Canceled)
- (Previously Presented) The composition of claim 1, wherein the concentration of morphine base monohydrate is from about 18.75 mg/ml to about 300 mg/ml.
- (Previously Presented) The composition of claim 1, wherein the concentration of morphine base monohydrate is from about 37.5 mg/ml to about 150 mg/ml.

 (Previously Presented) The composition of claim 1, wherein morphine base monohydrate is purified morphine base monohydrate.

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- (Original) The composition of claim 1, wherein the concentration of the chitosan polymer is from about 2 mg/ml to about 7 mg/ml.
- 8. (Original) The composition of claim 1, wherein the concentration of the chitosan polymer is from about 4 mg/ml to about 6 mg/ml.
- 9. (Original) The composition of claim 1 wherein the antioxidant is selected from the group consisting of methanesulfonic acid, citric acid, sodium citrate, ascorbic acid, and sodium ascorbate.
- 10. (Original) The composition of claim 9, wherein the antioxidants are citric acid and sodium citrate, and the total amount of antioxidant is present in a range from about 20 to about 50% by weight/volume of the composition.
- 11. (Original) The composition of claim 9, wherein the antioxidants are ascorbic acid and sodium ascorbate, and the total amount of antioxidant is present in a range from about 40 to about 70% by weight/volume of the composition.
- 12. (Original) The composition of claim 9, wherein the antioxidant is methanesulfonic acid, and the amount of antioxidant is present in a range from about 10 to about 60% by weight/volume of the composition.
- 13. (Original) The composition of claim 1, wherein the antimicrobial agent is selected from the group consisting of benzalkonium chloride, disodium EDTA, sodium benzoate, and combinations thereof
- 14. (Previously Presented) The composition of claim 12, comprising an antimicrobial agent at a concentration of from about 0.0005% to about 0.5% by weight/volume of the composition.

- 15. (Previously Presented) The composition of claim 1, wherein the concentration of antimicrobial agent is from about 0.005% to about 0.5% by weight/volume of the composition.
- 16. (Original) The composition of claim 1, wherein the transmucosal delivery is selected from the group consisting of nasal, buccal, rectal, vaginal, and ocular modes of administration.
- $17. \ (Original) \qquad The \ composition \ of \ claim \ 1, \ wherein \ the \ transmucosal \ delivery \ is$ by nasal administration.
- (Withdrawn) The composition of claim 1, wherein the composition is prepared under nitrogen gas by
- (a) mixing the morphine and acid, polymer, and antimicrobial agents, wherein each ingredient is mixed into the solution for at least 5 minutes;
 - (b) adding the antioxidants, wherein the pH is from about 3.0 to about 5.0;
 - (c) adjusting the final batch volume with water to form a final solution; and
 - (d) filtering the solution with a pre-sterilized micron filter.
- 19. (Withdrawn) The composition of claim 18, wherein the pre-sterilized micron filter is about a 0.2 micron filter.
- 20. (Previously Presented) The composition of claim 1, wherein the composition yields about 18.75 to about 300 microgram of morphine base monohydrate per 100 microliter nasal spray.
- 21. (Currently Amended) A method of administering a controlled release morphine medicament, wherein the medicament is administered transmucosally to a subject in need thereof, said medicament comprising:

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- (a) an therapeutically analgesically effective amount of morphine base monohydrate;
- (b) an effective amount of a controlled release chitosan polymer <u>in an amount</u> effective to provide substantially linear absorption rates upon administration; and optionally comprising:
 - (c) one or more antimicrobial agents;
 - (d) one or more antioxidants; and
 - (e) water

wherein the molecule to molecule ratio of morphine base monohydrate to the controlled release chitosan polymer ranges from about 1:1 to about 100,000:1 to provide the substantially linear absorption rates upon administration.

- 22. (Previously Presented) The method of claim 21, wherein the morphine base monohydrate is purified morphine base monohydrate.
 - 23. (Original) The method of claim 21, wherein the subject is human.